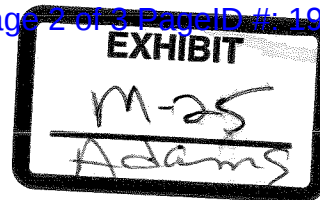


# **EXHIBIT M25**



**From:** Chuck Koon  
**Sent:** Sunday, April 27, 2008 10:23 PM  
**To:** Hal Korman <Hal.Korman@mylanlabs.com>  
**Cc:** Mike Adams <madams@mylanlabs.com>; Patricia Latzo <patricia.latz@mylanlabs.com>; Rajiv Malik <Rajiv.Malik@mylanlabs.com>  
**Subject:** Actavis (Amide) Recall and FDA Inspection

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Hal,

I wanted to follow-up on the audit status of Amide and also give you some idea of the nature of the current FDA inspection.

Well over a year ago, we (Quality) presented a review of the compliance issues at Amide to the outsourced committee that was meeting regularly at that time. This included a review of the 483's, warning letters, and consent decrees at that site that we had discovered on our own. As part of that review, we contacted Amide repeatedly to discuss these FDA actions and to request information regarding any other actions that we didn't know about at the time. Though Amide was always required to notify us of any FDA actions, not only did they not ever do that but, when we contacted them we got nowhere. It took Trish finding and making contact with the Global Head of Quality for Actavis before we could get the site Quality group to even commit to allow us to review some of the many regulatory documents. Even with this hesitant commitment, Amide said we could see them on-site only and wouldn't provide them otherwise. So, we sent two auditors to the Totowa site to retrieve these documents and try to review them with their Quality Group. Our auditors were successful in retrieving the documents but, got very little direct time with the Quality Director there as he made himself mostly unavailable. That visit served to reinforce the feeling that it would be best to pursue moving the product from Amide if possible. The outsourced committee was reviewing the language in the 10-year contract to see if there was any "out" for us. The deal was originally signed in 1999 and has a manufacturing transfer clause that was never pursued because Bertek's manufacturing never materialized. So, in the end, the product remained at Amide. As recently as a couple months ago, we contacted Amide to schedule an audit date but, the date kept getting cancelled by Amide and then the FDA showed up and they weren't able to host an audit anyhow.

What we know about the current FDA inspection is that Amide has constructed a new production building and as part of the Qualification ran Digitek validation batches in the new facility. This was done because Digitek is a simple direct-compression process and should have been an easy first product to transfer into the new building. In order to open the new facility, Actavis (Amide) requested FDA perform a PAI. FDA obliged and that is the reason this inspection started about 6 weeks ago. The inspection has obviously now expanded beyond just a PAI for a new facility into a review of the systems used to control processes. When our business group got notice that the recall was going to happen, Actavis' business contact notified us that Actavis' U.S. Head of Quality would be calling. Mike Adams and I spoke to her on the phone and she described that the PAI had been going on for 6 weeks and that they were being "beaten up" by FDA. She stated that the reason the recall was expanded to all Digitek was that FDA felt that there weren't adequate controls on their tablet presses to assure that the double-thick tablet issue couldn't have happened previously. We asked the U.S. Quality lady if this was revealed at the close-out of the inspection and she stated that the inspection was still ongoing and had not been closed-out as of yet and expected the inspection to continue into the next week. She also made it clear that other products were being recalled, that the new facility would not be approved, and that their dietary supplement operation would have to halt manufacturing. So,

it would appear that FDA is focusing on Amide's systems to control and ensure product quality rather than simply having concerns over just one investigation. This approach could have far-reaching impact into Amide's ability to commence manufacture at the Actavis Totowa Little Falls, NJ site. We will need to contact the U.S. Quality Head tomorrow to find out if anything else has transpired regarding their site (though she has not answered her phone since the first and only conversation with her).. In addition, on Friday, Actavis requested Mylan to provide any complaints for any other Actavis products we carry even if they are not made at Actavis Totowa. This request was made to satisfy an FDA request. We complied and our Product Safety/Risk Mgmt. group sent the info. to Actavis on Friday afternoon for the product "Acticin" which is permethrin cream made at Actavis' Lincolnton, NC site. From this request, we may begin to see that FDA is going to start reviewing other Actavis sites to determine if there are the same types of violations elsewhere and thus broader systemic issues.

To assure that all of our Mylan players are aware of the recall status, Trish has requested that I pull together a meeting for Monday afternoon to include the key participants in the process; Mike Adams, Cass Bird, and Ann Wolfe who've led the charge from the MPI side, and those that should be aware and kept up to date from Sales, Legal, BD/Outsourcing, and Ops. (Vince and yourself). I'll send out a meeting notice in the morning with a call-in number so that everyone can participate.

Please let me know if you have any questions at all.

Thanks,  
Chuck

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Sent from my BlackBerry Wireless Handheld